

526 Rec'd PCT/PTO 17 JUL 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
REQUEST FOR FILING NATIONAL PHASE OF  
PCT APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495



00909

To: Hon. Commissioner of Patents  
Washington, D.C. 20231

Atty Dkt: P 0281558 /Z 70475/UST  
M# /Client Ref.

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)

Date: July 17, 2001

From: Pillsbury Winthrop LLP, IP Group:

This is a **REQUEST** for **FILING** a PCT/USA National Phase Application based on:

International Application

PCT/GB00/00278

↑ country code

2. International Filing Date

1 February 2000  
Day MONTH Year

3. Earliest Priority Date Claimed

6 February 1999  
Day MONTH Year  
(use item 2 if no earlier priority)

Measured from the earliest priority date in item 3, this PCT/USA National Phase Application Request is being filed within:

- (a) ☐ 20 months from above item 3 date  
(b) ☒ 30 months from above item 3 date,  
(c) Therefore, the due date (unextendable) is August 6, 2001

Title of Invention DRUG COMBINATIONS COMPRISING (E)-7-[4-(4-FLUOROPHENYL)-6-ISOPROPYL-2-METHYLSULFONYL] AMINO] PYRIMIDIN-5-YL] (3R,5S)-3,5-DIHYDROXYHEPT-6-ENOIC ACID AND AN INHIBITOR, INDUCER OR SUBSTRATE OF P450ISOENZYME 3A4

Inventor(s) RAZA, Ali et al

Applicant herewith submits the following under 35 U.S.C. 371 to effect filing:

- ☒ Please immediately start national examination procedures (35 U.S.C. 371 (f)).

☒ **A copy of the International Application** as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (file if in English but, if in foreign language, file only if not transmitted to PTO by the International Bureau) including:

- a. ☒ Request;  
b. ☒ Abstract;  
c. 45 pgs. Spec. and Claims;  
d.        sheet(s) Drawing which are ☐ informal ☐ formal of size ☐ A4 ☐ 11"

9. ☒ **A copy of the International Application has been transmitted by the International Bureau.**

10. **A translation of the International Application** into English (35 U.S.C. 371(c)(2))

- a. ☐ is transmitted herewith including: (1) ☐ Request; (2) ☐ Abstract;  
(3)        pgs. Spec. and Claims;  
(4)        sheet(s) Drawing which are: ☐ informal ☐ formal of size ☐ A4 ☐ 11"

- b. ☐ is not required, as the application was filed in English.  
c. ☐ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.  
d. ☐ Translation verification attached (not required now).

11. ☒ Please see the attached Preliminary Amendment
12. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., before 18th month from first priority date above in item 3, are transmitted herewith (file only if in English) including:
13. ☒ PCT Article 19 claim amendments (if any) have been transmitted by the International Bureau
14. ☐ Translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., of claim amendments made before 18th month, is attached (required by 20th month from the date in item 3 if box 4(a) above is X'd, or 30th month if box 4(b) is X'd, or else amendments will be considered canceled).
15. **A declaration of the inventor (35 U.S.C. 371(c)(4))**  
 a. ☐ is submitted herewith ☐ Original ☐ Facsimile/Copy  
 b. ☒ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.
16. **An International Search Report (ISR):**  
 a. Was prepared by ☒ European Patent Office ☐ Japanese Patent Office ☐ Other  
 b. ☒ has been transmitted by the international Bureau to PTO.  
 c. ☒ copy herewith (1 pg(s).) ☒ plus Annex of family members (1 pg(s).).
17. **International Preliminary Examination Report (IPER):**  
 a. ☒ has been transmitted (if this letter is filed after 28 months from date in item 3) in English by the International Bureau with Annexes (if any) in original language.  
 b. ☒ copy herewith in English.  
 c.1 ☐ IPER Annex(es) in original language ("Annexes" are amendments made to claims/spec/drawings during Examination) including attached amended:  
 c.2 ☐ Specification/claim pages # \_\_\_\_\_ claims # \_\_\_\_\_  
 Dwg Sheets # \_\_\_\_\_  
 d. ☐ Translation of Annex(es) to IPER (required by 30<sup>th</sup> month due date, or else annexed amendments will be considered canceled).
18. **Information Disclosure Statement including:**  
 a. ☒ Attached Form PTO-1449 listing documents  
 b. ☐ Attached copies of documents listed on Form PTO-1449  
 c. ☒ A concise explanation of relevance of ISR references is given in the ISR.
19. ☐ **Assignment** document and Cover Sheet for recording are attached. Please mail the recorded assignment document back to the person whose signature, name and address appear at the end of this letter.
20. ☐ Copy of Power to IA agent.
21. ☐ **Drawings** (complete only if 8d or 10a(4) not completed): \_\_\_\_\_ sheet(s) per set: ☐ 1 set informal;  
☐ Formal of size ☐ A4 ☐ 11"
22. Small Entity Status ☒ is **Not** claimed ☐ is claimed (pre-filing confirmation required)
- 22(a) \_\_\_\_\_ (No.) Small Entity Statement(s) enclosed (since 9/8/00 Small Entity Statements(s) not essential to make claim)
23. **Priority** is hereby claimed under 35 U.S.C. 119/365 based on the priority claim and the certified copy, both filed in the International Application during the international stage based on the filing in (country) GREAT BRITAIN of:
- |     | Application No. | Filing Date      | Application No. | Filing Date |
|-----|-----------------|------------------|-----------------|-------------|
| (1) | 9902593.4       | February 6, 1999 | (2)             | 9921063.5   |
| (3) | 9921064.3       | Sept. 8, 1999    | (4)             |             |
| (5) |                 |                  | (6)             |             |
- a. ☒ See Form PCT/IB/304 sent to US/DO with copy of priority documents. If copy has not been received, please proceed promptly to obtain same from the IB.
- b. ☐ Copy of Form PCT/IB/304 attached.

RE: USA National Phase Filing of GB00/00278

24. Attached: 2 copies of Form PCT/IB/306

25. Per Item 17.c.2, cancel original pages # \_\_\_\_\_, claims # \_\_\_\_\_, Drawing Sheets # \_\_\_\_\_

26. **Calculation of the U.S. National Fee (35 U.S.C. 371 (c)(1)) and other fees is as follows:**  
Based on amended claim(s) per above item(s) ☐ 12, ☐ 14, ☐ 17, ☐ 25 (hilitte)

966/967  
964/965  
968/969

Total Effective Claims  
Independent Claims

If any proper (ignore improper) Multiple Dependent claim is present,

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): **→→→→→ BASIC FEE REQUIRED, NOW →→→→→**

A. If country code letters in item 1 are not "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"

See item 16 re:

1. Search Report was not prepared by EPO or JPO ----- add\$1000/\$500
2. Search Report was prepared by EPO or JPO ----- add\$860/\$430

+860

960/961  
970/971

**SKIP B, C, D AND E UNLESS country code letters in item 1 are "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"**

→ ☐ B. If USPTO did not issue both International Search Report (ISR) and (if box 4(b) above is X'd) the International Examination Report (IPER), -----

add\$1000/\$500

+0

960/961

(only) → ☐ C. If USPTO issued ISR but not IPER (or box 4(a) above is (one) X'd), -----

add\$710/\$355

+0

958/959

(these) → ☐ D. If USPTO issued IPER but IPER Sec. V boxes not all 3 (4) YES, -----

add\$690/\$345

+0

956/957

→ ☐ E. If international preliminary examination fee was paid to USPTO and Rules 492(a)(4) and 496(b) satisfied (IPER Sec. V all 3 boxes YES for all claims), -----

add \$100/\$50

+0

962/963

**SUBTOTAL =**

\$860

+0

(581)

27. If Assignment box 19 above is X'd, add Assignment Recording fee of ----\$40

28. Attached is a check to cover the -----

**TOTAL FEES**

\$860

Our Deposit Account No. 03-3975  
Our Order No. 009901

C# 0281558 M#



00909

**CHARGE STATEMENT:** The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 and 492 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown above for which purpose a duplicate copy of this sheet is attached.  
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed

**Pillsbury Winthrop LLP**  
**Intellectual Property Group**

By Atty: Donald J. Bird

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Atty/Sec: DJB/mhn

**NOTE:** File in duplicate with 2 postcard receipts (PAT-103) & attachments.